REMARKS

Reconsideration of the present application is respectfully requested.

Claims 34-73 were pending. Claims 34, 39, 40, 62-73 were amended, and claims 74-80 were added, to simplify the claim language and/or more fully claim that what Applicants regard as their invention. Support for new claims is found through out the specification, no new matter was added.

Double Patenting Rejection

The examiner has provisionally rejected claims 34-73 of the instant application under 35 U.S.C. 101 as claiming the same invention as that of (i) claims 209-230 of allowed Application No. 10/127,817 ("the '817 application") and (ii) claims 209-224 of allowed Application No. 10/770,969 ("the '969 application," now U.S. Pat. No. 6,900,241 issued May 31, 2005). Applicants respectfully traverse the rejections.

Rejection over the '817 application

Applicant respectfully submit that the subject group of humans or veterinary animals treated according to the methods described in the '817 application is not the same as the subject group treated according to the method of the instant claims. The test for the "same invention" double patenting under 35 USC § 101 is "whether one of the claims being compared could be literally infringed without literally infringing the other. If it could be, the claims do not define the same invention." Chisum on Patents, § 9.03[3][b] citing *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The present claims recite administering the compounds of the invention to subjects in need of anti-platelet therapy. Examples of such subjects include subjects suffering from, or at risk of, coronary disorders (e.g. angina, heart attack/myocardial infarction), stroke, diabetes, sickle cell disease, Kawasaki's disease, retinopathy (non-inflammatory degenerative disease of the retina), pre-eclampsia etc. While some of these subjects may be suffering from, or are at risk of atherosclerosis, thrombosis, heart attack, stroke and resultant vascular circulation disorders (as

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recited in claims 209-230 of the '817 application), others are not. For example, antiplatelet drugs may be used in pregnant women to reduce pre-eclampsia, preterm birth, stillbirth and neonatal death (see attached abstract by Duley *et al.*, *Evidence-Based Med.*, 2001, 6:107). Treatment of pregnant women suffering from, or at risk of, pre-eclampsia is not encompassed by the treatment according to the '817 application. Withdrawal of the rejection is, therefore, believed to be in order; and such action is respectfully requested.

With respect to instant claims 48-61, which specifically recite anti-platelet therapy of a human suffering from, or at risk of, atherosclerosis, Applicants submit that they, also, are not directed to the same invention as the invention covered by the '817 application claims. This is because atherosclerosis is a complex disease which starts with endothelial damage followed by plaque buildup (possibly followed by burst, tear or rupture of the plaque), which endothelial damage may be caused by a variety of factors such as elevated levels of cholesterol and triglycerides, high blood pressure, tobacco smoke, and diabetes. (For detailed description of atherosclerotic processes see e.g. www.americanheart.org). Various pathways leading to atherosclerosis are described in the present specification e.g. at page 9, lines 33-38; page 10, lines 1-12; page 11, lines 6-9; page 12, lines 1-11; page 13, lines 7-12 and 13-22; page 14, lines 27-38, and page 15, lines 1-10 (*see also* Figs. 2A-C). Because of the complexity of causative factors and underlying mechanisms, not every patient suffering from, or at risk of, atherosclerosis would benefit from anti-platelet therapy. In other words, the patient group recited in present claims 48-61 represents a *subgroup* of patients recited in claims 209-230 of the '817 application.

In summary, claims of the '817 application can be literally infringed without infringing the claims of the present application and *vise versa*. Therefore, the same invention is not being claimed. Withdrawal of the rejection under 35 USC § 101 is respectfully requested.

Rejection over the '969 application

The '969 application, and the above discussed '817 application, both recite treatment of the same group of subjects. Accordingly, Applicants respectfully traverse the rejection of the same invention double patenting over the '969 application claims for the reasons discussed

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above. Additionally, claims 209-218 of the '969 application recite administration of a *monomer*, and are therefore directed to a different subject matter than the one covered by the instant claims, which recite administration of an *oligomer*. Withdrawal of the rejection is respectfully requested.

Terminal Disclaimer

Applicants submit herewith a Terminal Disclaimer over the parent patent, U.S. 6,717,059.

Conclusion

In view of the above remarks, Applicants believe that the application is in condition for allowance. Such action is respectfully requested.

Respectfully submitted,

Date: August 9, 2005

Nada Jain
Reg. No. 41,431

SEND CORRESPONDENCE TO:

NADA JAIN, P.C.
560 White Plains Road
Tarrytown, NY 10591
Phone: 914-333-0610 x150

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Review: antiplatelet drugs reduce pre-eclampsia, preterm birth, and stillbirth or neonatal death

Duley L, Henderson-Smart D, Knight M, et al.Antiplatelet drugs for prevention of pre-eclampsia and its consequences: systematic review.BMJ 2001 Feb 10;322:329–33. [Abstract/Free Full Text]

QUESTION: In pregnant women at risk for pre-eclampsia, how effective are antiplatelet drugs in preventing pre-eclampsia and its complications?

Data sources

Studies were identified by searching the Cochrane Pregnancy and Childbirth Group register of trials, the Cochrane Controlled Trials Register, and EMBASE/Excerpta Medica (1994–9) and by handsearching conference abstracts.

Study selection

Studies were selected if they were randomised controlled trials comparing antiplatelet drugs with placebo or no antiplatelet drug in women at risk for developing pre-eclampsia. Exclusion criteria were having no clinical data available, inadequate randomisation, <80% follow up of patients, or having participants at very low risk for pre-eclampsia.

Data extraction

Data were extracted on study validity (allocation concealment), patient risk for developing pre-eclampsia (high or moderate), length of gestation (< or ≥20 wks), dose of aspirin (≤75 mg or >75 mg), whether the study was placebo controlled, and outcomes (for women: pre-eclampsia, caesarean section, antepartum haemorrhage, serious maternal morbidity, and rare adverse events; for infants: death [stillbirth, neonatal, or infant], preterm birth [<37 wks], small for gestational age, bleeding episodes, and infant development measures).

Main results

39 trials (30 563 women) were included. Most trials (28 802 women) compared aspirin with placebo. Fewer patients receiving antiplatelet drugs had pre-eclampsia than control group patients (table). The relative benefit was not affected by risk status, dose of aspirin, length of gestation at trial entry, or use of

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a placebo. The groups did not differ for the other maternal outcomes of eclampsia (9 trials), maternal death (2 trials), or caesarean section (17 trials). Fewer preterm births, stillbirths, or neonatal deaths occurred in the antiplatelet drug group (table). The groups did not differ for small for gestational age births (25 trials), intraventricular haemorrhage (8 trials), other neonatal bleeding (6 trials), or infant development (1 trial).

View this table: [in this window] [in a new window] *Antiplatelet drugs v placebo or no antiplatelet drug for women at risk for pre-eclampsia**

Conclusion

In pregnant women at risk for pre-eclampsia, antiplatelet drugs prevent pre-eclampsia and reduce the risk for preterm birth and stillbirth or neonatal death.

Footnotes

Source of funding: no external funding.

For correspondence: Dr L Duley, Resource Centre for Randomised Trials, Institute of Health Sciences, Oxford OX3 7LF, UK. Fax +44 (0)1865 227173.

Commentary

Mary E Hannah, MDCM

University of Toronto Toronto, Ontario, Canada

Good biological rationale exists to explain why low doses of antiplatelet drugs should reduce the likelihood of pre-eclampsia, preterm birth, and their perinatal consequences among women at risk for pre-eclampsia. Small, randomised, controlled trials seemed to confirm the hypothesis, but subsequent large trials did not.[1] The discrepancy between the earlier positive results and the later negative ones was attributed to publication bias. In this systematic review and meta-analysis done as part of the work of the Cochrane Collaboration,[2] Duley *et al* have found that antiplatelet drugs confer important and statistically significant benefits on mothers at risk for pre-eclampsia and on their infants, without any identified risks. The review is powerful because it includes studies that are methodologically strong and because the total number of women enrolled is very large (>30 000). The findings of a modest reduction in risk for pre-eclampsia, preterm birth, and death of the fetus or baby with antiplatelet treatment are important. Additional information will come from the pooling of data from the existing trials about the effects of higher doses of aspirin, treatment among higher risk women, and treatment at an earlier point in gestation.

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Compelling evidence exists to recommend general and widespread use of low dose aspirin (<75 mg) beginning after 12 weeks of pregnancy for women at risk for pre-eclampsia. The women most likely to benefit are those with a history of pre-eclampsia, chronic hypertension, or such medical problems as diabetes or renal disorders. Women with more moderate risk factors, however, may also benefit (eg, first pregnancy, multiple pregnancy, family history of pre-eclampsia, teenaged mother, abnormal result on uterine artery Doppler scan or rollover test, or mild increase in blood pressure without proteinuria). These women should also be offered this effective treatment.

References

1. CLASP 1994 CLASP (collaborative low-dose aspirin study in pregnancy) Collaborative Group. CLASP: a randomised trial of low-dose aspirin for the prevention and treatment of pre-eclampsia among 9364 pregnant women. *Lancet* 1994;343:619–29.[Medline]
2. Knight M, Duley L, Henderson-Smart DJ, *et al.* Antiplatelet agents for preventing and treating pre-eclampsia. *Cochrane Database Syst Rev* 2000;(2):CD000492.[Medline]

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